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5/21/03/1637

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Maes et al.

Serial No.: 09/578,361

Filed: May 24, 2000

For: METHOD OF PARALLEL SCREENING FOR INSERTION MUTANTS AND A KIT TO PERFORM THIS METHOD

Confirmation No.: 4901

Examiner: T. Strzelecka

Group Art Unit: 1637

Attorney Docket No.: 2676-4409US

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REPLY BRIEF

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Sir:

This Reply Brief responds to the Examiner's Answer mailed on March 7, 2003. A reply brief may be filed within two months from the date of an Examiner's Answer. 37 C.F.R. § 1.193(b)(1). This Reply Brief is submitted in TRIPLICATE.

I. A *PRIMA FACIE* CASE OF OBVIOUSNESS HAS NOT BEEN ESTABLISHED

A. Each and Every Element of the Pending Claims are Not Taught or Suggested by the Cited References

A *prima facie* case of obviousness has not been established since the cited references do not teach or suggest each and every element of pending independent claims 1 and 19. As argued in the Brief on Appeal, "Dellaporta does not teach or suggest 'amplifying **each of said plurality of insertion element flanking sequences** from said block, row and column pools'" as required by claims 1 and 19. *Brief on Appeal* dated December 2, 2002, page 6.

In response to the Appellants' arguments, the Examiner stated "[a]s to the limitation of amplifying each of the plurality of insertion element flanking sequences, Dellaporta teaches amplification by inverse PCR (iPCR) ..., which is claimed by the Appellants as an embodiment which results in amplification of each of the insertion element flanking sequences (claims 2 and 3). Therefore it would be reasonable to assume that [Dellaporta] would achieve this result because he uses exactly the same method of amplification as claimed by Appellants." *Examiner's Answer* dated March 7, 2003, page 12.

However, it is not the method of amplification that results in the amplification of each "of said plurality of insertion element flanking sequences from said block, row and column pools" as claimed by the Appellants, but it is the primers used in the amplification method that results in the amplification of each of the insertion element flanking sequences. As stated in Dellaporta "[t]he advantage of a technique such as IPCR, with respect to the current invention, is that using a single primer set **one may amplify a representative sample of insertion junctions from a particular group of individuals**." U.S. Pat. 6,013,486, Col. 12, lines 5-8 (Emphasis added). Thus, the primers in Dellaporta only amplify a **representative sample** of insertion junctions from the group and do not amplify **each** of the plurality of insertion element flanking sequences from the block, row and column pools as required by Appellants' claims 1 and 19.

Since each of claims 1 and 19, and the claims depending therefrom, include the element of amplifying each of the plurality of insertion element flanking sequences and the cited

references do not teach or suggest each and every element of claims 1 and 19, a *prima facie* case of obviousness cannot be established.

B. Lack of Suggestion or Motivation to Combine Cited References

In the Brief on Appeal, the Appellants stated "[t]he motivation provided by the Examiner to combine Dellaporta and Koes et al. does not suggest a desirability for combining the references, but merely restates why Koes et al. prefers a 'one-step three-dimensional screening over the three repeated rounds of one-dimensional screening.'" *Brief on Appeal* at page 8. In response to the Appellants' argument, the Examiner stated "[b]oth Dellaporta and Koes et al. provide compelling motivation for using pooling of samples: efficient screening for desired sequences. Koes et al. provide additional motivation for using 3D pooling as being less prone to produce false positive signals and less laborious than one-dimensional screening." *Examiner's Answer* at page 14.

Appellants contend the Examiner is using a hindsight reconstruction of the Appellants invention to formulate the obviousness rejections since the Examiner has not shown "reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USQP2d 1453 (Fed. Cir. 1998). The Examiner has merely restated why the authors of Koes et al. prefer a one-step three-dimensional screening over three repeated rounds of one-dimensional screening and has not explained the specific understanding or principle that would motivate a skilled artisan with no knowledge of the Appellants' invention to combine the 3D block, row and column pools of Koes et al. with the screening method of Dellaporta.

Thus, without a suggestion or motivation to combine the reference teachings, a *prima facie* case of obviousness cannot be established.

C. Dellaporta Specifically Teaches Away From Koes et al.

The Appellants further articulated in the Brief on Appeal that Dellaporta specifically discourages the teachings of Koes et al. and amounts to a teaching away. *See, Brief on Appeal* at

page 8. In response to the Appellants' argument, the Examiner stated "Koes et al. is relied on for the teaching of a 3D pooling technique, not for the amplification method, whereas Dellaporta is relied on for teaching of the amplification of insertion junctions." *Examiner's Answer* at page 12.

However, the mere identification of elements in the cited references that appear related to the elements of the Appellants' claims does not negate patentability. There must be a motivation to combine the references and as previously articulated herein, no motivation exists. As stated by the Federal Circuit "[i]f identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *In re Rouffet* at 1357. The Examiner has merely identified elements in the cited references that are related to the elements of the Appellants' claims and combined them without a suggestion or motivation, when, in fact, Dellaporta teaches away from the combination of the two references.

A reference is said to teach away "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference" and that a "reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). Thus, the statement in Dellaporta that recites "the need for individual amplifications of each gene being investigated represents a significant hindrance when seeking to identify more than a small number of insertional mutants" is a clear teaching away that would discourage one of skill in the art from combining the reference teachings.[1] U.S. Pat. 6,013,486, Col. 1, lines 57-60.

Accordingly, each of pending claims 1-17 and 19-22 define patentable subject matter.

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[1] Dellaporta specifically references Koes et al. as a reference that uses individual amplifications of each gene being investigated. *See*, U.S. Pat. 6,013,486 at Col. 1, lines 35-47.

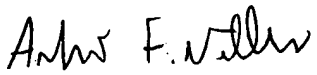
II. A *PRIMA FACIE* CASE OF OBVIOUSNESS HAS NOT BEEN ESTABLISHED WITH REGARD TO CLAIM 4

In the Examiner's Answer, the Examiner asserted "Sour et al. teach amplification of each of the insertion flanking sequences, since they teach iPCR (see discussion for claims of Group I)." *Examiner's Answer* at page 15. However, as previously articulated herein, the method of iPCR does not result in the amplification of each of the plurality of insertion element flanking sequences since it is the primers that dictate what regions of DNA are amplified. Therefore, even though Sour et al. discloses iPCR, it does not stand to reason that Sour et al. also discloses amplifying each of the plurality of insertion element flanking sequences from said block, row and column pools using at least one primer derived from a sequence of a nucleic acid of a nucleic acid insertion element of said plurality of nucleic acid insertion elements as required by claims 1 and 19.

III. CONCLUSION

In view of the remarks herein, each of claims 1-17 and 19-22 define patentable subject matter. Contrary to the Examiner's arguments, the invention set forth in claims 1-17 and 19-22 of the current application is not made obvious by the cited references of record as asserted by the Examiner for the foregoing reasons, the argument in the Appellant's Appeal Brief and the various arguments made during prosecution of the pending application. Thus, the Examiner's rejections of claims 1-17 and 19-22 should be withdrawn.

Respectfully submitted,



Andrew F. Nilles
Registration No. 47,825
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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